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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,153

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WILLNER9A

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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT

PAPER NUMBER

1635

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,153	Applicant(s) WILLNER ET AL.	
	Examiner Tracy Vivlemore	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009 and 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-10,12 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

Election/Restrictions

Claims 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 11, 2009.

Claims 2-4, 13 and 14 have been canceled. Claims 1, 5-10 and 12 are under examination.

Claim Rejections - 35 USC § 103

Claims 1, 5-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usman et al. (US 2002/0102568, of record), Travascio et al. (Chemistry & Biology 1998, of record) and Kawaguchi et al. (US 2002/0076696, of record).

The claims are directed to a method for determining the presence of a nucleic acid in a sample by contacting a catalytic polynucleotide that is a peroxidase DNAzyme complexed with hemin with the sample such that it binds the nucleic acid, providing assay conditions to allow the catalytic polynucleotide to produce an optically detectable signal in the presence of the nucleic acid and determining the presence of the nucleic

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acid in the sample by detection of that signal. In specific embodiments the optically detectable signal is produced by a light emitting reaction such as that of luminol or is production of a colorimetric product such as that produced by ABTS. In other embodiments the nucleic acid is immobilized on a solid surface such as a bead or the method is performed quantitatively by comparing the optically detectable signal with a calibration scale.

Usman et al. teach nucleic acid sensor molecules that detect analytes such as nucleic acids and produce a detectable signal. Use of these sensor molecules is shown in figures 5 and 7, which show the combination of a catalytic nucleic acid and a target nucleic acid. Upon binding of the target, the catalytic nucleic acid is able to cleave a reporter sequence and produce a detectable signal (in figure 5, a fluorescent signal). Usman et al. teach the sensor molecules can be attached to a solid surface and that this surface can be a bead (see figure 23 and paragraph 109). Usman et al. teach at paragraph 44 that the signal is produced by a reporter molecule, which can be chromogenic (i.e., colorimetric detection), fluorescent, or chemiluminescent. At paragraph 174 Usman et al. teach kits for detection of an analyte, one component of which is a standardized solution to be used in making of a calibration curve. At paragraph 193 Usman et al. teach that the catalytic nucleic acid can have a variety of activities, including peroxidase activity, but do not explicitly exemplify a peroxidase and do not teach one that complexes with hemin.

Travascio et al. teach a catalytic DNA sequence that exhibits peroxidase activity when complexed with hemin. Travascio et al. further teach the use of ABTS as a

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detectable signal and the use of a calibration curve for quantification of the signal (see materials and methods).

At the time the invention was made those of ordinary skill in the art were aware that ABTS and luminol were two alternative means for detecting peroxidase activity. See Kawaguchi et al., who at paragraph 46 teach that when peroxidase is used as a labeling enzyme, reagents for detecting or quantitatively determining the activity of the enzyme include hydrogen peroxide and a color reagent such as 2,2'-azino-bis(3-ethylbenzothiazoline)-6-sulfonic acid (ABTS) or a luminescence reagent such as luminol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the sensor molecules taught by Usman et al. to have peroxidase activity and to use the peroxidase catalytic DNA taught by Travascio et al. One would have reason to do so because Usman et al. teach sensor molecules that are generally useful and explicitly teach they can be made with a variety of activities, including peroxidase, and given the teachings of Travascio et al. one would recognize use of this particular peroxidase as a matter of simple substitution of known elements. Because Kawaguchi et al. teach that ABTS and luminol are functional equivalents used to detect peroxidase activity, one of ordinary skill in the art would find it obvious to use luminol in place of ABTS when detecting peroxidase activity using the catalytic DNA taught by Travascio et al. and would have a reasonable expectation that this substitution would provide predictable results. It would further have been obvious to one of ordinary skill in the art at the time the invention was made to use the nucleic acid sensor molecules taught by Usman et al. in a detection method wherein the analyte is

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attached to a solid surface. Usman et al. teach that the sensor molecule can be attached to a surface and that these sensors can be used to detect nucleic acid sequences. One of ordinary skill in the art would immediately recognize that such a detection method would also be feasible when the target nucleic acid is attached to the surface in place of the sensor portion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi, can be reached on 571-272-3311. The central FAX Number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tracy Vivlemore
Primary Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635